

REMARKS/ARGUMENTS

Favorable reconsideration of this application is requested in view of the amendments above and the remarks which follow.

Disposition of Claims

Claims 12-15, 17, 18, and 24 are pending in this application.

Rejections under 35 U.S.C. §103

A. Claims 12-15, 17, 18, and 24 were rejected under 35 U.S.C. §103(a) as being obvious over Wong et al. (U.S. Patent No. 5,324,280). Reconsideration of this rejection is respectfully requested.

Claim 12 recites a sustained-release dosage form for the delivery of a progestogenic steroid. The dosage form comprises a capsule and a self-emulsifying drug formulation contained within a first portion of the capsule, wherein the self-emulsifying drug formulation contains a progestogenic steroid. The dosage form further comprises an expandable layer contained within a second portion of the capsule, wherein the expandable layer is positioned such that the self-emulsifying drug formulation can be expelled from the capsule upon expansion of the expandable layer. The dosage form further comprises a semipermeable membrane formed over at least a portion of an outer surface of the capsule.

Wong et al. teach an osmotic dosage form wherein a drug formulation is contained within a capsule. The capsule itself is encapsulated within a hydro-activated layer. This is in contrast to the invention recited in claim 12 wherein the expandable layer is located inside the capsule. The Examiner admits that Wong et al. teach that the liquid formulation is initially essentially free of direct contact with a hydro-activated expansion composition. Therefore, one of ordinary skill in the art upon reviewing the Wong et al. patent would not be motivated to locate the expandable layer inside the capsule since Wong et al. teach that the liquid formulation is initially essentially free of direct contact with a hydro-activated expansion composition.

Applicant currently does not have a side-by-side comparison of the release profiles of the dosage form recited in claim 12 and the dosage form of the Wong et al. patent. However,

Applicant believes that there would be significant mixing between the hydro-activated layer and the drug formulation for the dosage form disclosed in Wong et al. if the drug formulation can self-emulsify. A self-emulsifying formulation is a formulation that itself is not an emulsion but forms an emulsion upon mixing with water. It is preferable that the self-emulsifying drug formulation forms the emulsion in-situ upon delivery to an environment of operation.

In Wong et al., the interface between the hydro-activated layer and the capsule is large since the hydro-activated layer encapsulates the capsule. This would cause the capsule to dissolve rapidly, leading to significant mixing between the hydro-activated layer and the drug formulation. This significant mixing between the drug formulation and the hydro-activated layer could lead to an erratic release profile and a very high amount of drug residue after release if the drug formulation can self-emulsify.

Claim 12 recites that the expandable layer is positioned in a second portion of the capsule while the drug formulation is positioned in a first portion of the capsule. This localizes and minimizes interaction between the drug formulation and the expandable layer, thereby preventing significant mixing between the aqueous liquid in the expandable layer and drug formulation. Significant hydration of the capsule is also prevented. Further, the position of the expandable layer relative to the drug formulation facilitates transmission of pressure from the expandable layer to the drug formulation, thereby enhancing release of the drug formulation from the capsule.

From the foregoing, it is clear that claim 12 is not obvious over Wong et al. Withdrawal of the rejection of claim 12 over Wong et al. is respectfully requested. Claims 13-15, 17, 18, and 24, being dependent from claim 12, are likewise patentable over Wong et al. in view of the foregoing arguments. Withdrawal of the rejection of these claims is respectfully requested.

B. Claims 12-15, 17, 18, and 24 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (U.S. Patent No. 6,458,373) in view of Wong et al. Reconsideration of this rejection is respectfully requested.

Lambert et al. teach an α -tocopherol emulsion in the form of a self-emulsifying system encapsulated in a soft or hard gelatin capsule. Lambert et al. do not teach or disclose that an expandable layer is also contained within the capsule. In contrast, claim 12 recites a self-

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emulsifying drug formulation and an expandable layer contained within the same capsule. This allows controlled release of the drug as well as minimizes undesirable mixing between the drug formulation and the expandable layer. Wong et al., which has been discussed above, fail to overcome the deficiencies in Lambert et al. Therefore, claim 12 cannot be obvious over Lambert et al. in view of Wong et al. Withdrawal of the rejection of claim 12 is respectfully requested. Claims 13-15, 17, 18, and 24, which depend from claim 12, are likewise patentable over the combination of Lambert et al. and Wong et al. Withdrawal of the rejection of these claims is also respectfully requested.

Conclusion

The rejected claims have been amended and/or shown to be allowable over the prior art. Applicant believes that this paper is fully responsive to each ground of rejection cited by the Examiner in the Office Action dated January 11, 2005, and respectfully requests that a timely Notice of Allowance be issued in this case.

Please apply any charges not covered or credits in connection with this filing to Deposit Account No. 50-3202 (ref. ARC2556N1).

Respectfully submitted,

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